

06/10/98 1c587 U.S. PTO

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June 10, 1998

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File No.: TOBINICK 3.0-006
Inventor(s): Dr. Edward L. Tobinick, M.D.
Title: METHOD OF EMPLOYING A FLASHLAMP FOR REMOVAL
OF HAIR, VEINS AND CAPILLARIES

Assignee: None

Dear Sir:

Enclosed herewith are the following documents in the above-identified application for a Letters Patent of the United States:

1	Pages of Abstract	X	Verified Statement for Small Entity Status
27	Pages of Specification		Declaration, Power of Attorney & Petition
8	Number of Claims		Two (2) return-addressed postcards
5	Sheets of Drawings		(PLEASE PROVIDE FILING DATE & SERIAL NUMBER)
none	Assignment for Recording		(attached to copy of this letter)

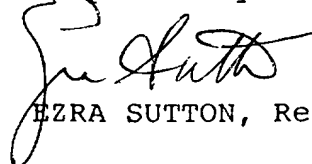
Check No. 2109 in the amount of \$395.00, calculated as follows:

Basic Fee (**Large Business \$790.00) (*Small Business \$395.00)	<u>\$395.00</u>
Additional Fees:	
Total number of claims <u>8</u>	--
Total number of claims in excess of 20, <u>--</u> times (**\$22)(*\$11)	--
Number of independent claims <u>2</u>	--
Number of independent claims minus 3, <u>--</u> times (**\$82)(*\$41)	--
Assignment recording fee (\$40)	--
Multiple dependent claims (**\$270) (*\$135)	--
TOTAL filing and assignment recording fees	<u>\$395.00</u>

CONVENTION DATE _____ for _____ Appln. No. _____
is claimed.

Priority Document: Enclosed Will follow

Respectfully submitted,



EZRA SUTTON, Reg No. 25,770

ES/jmt
Enclosures

**METHOD OF EMPLOYING A FLASHLAMP FOR
REMOVAL OF HAIR, VEINS AND CAPILLARIES**

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FIELD OF THE INVENTION

This invention relates to an improved method of employing a flashlamp for removal of hair, or veins or capillaries, and more particularly, it relates to a flashlamp emitting a series of sequential pulses of incoherent light energy, which are transmitted to the same area of the skin through an optical delivery system.

BACKGROUND OF THE INVENTION

Flashlamps allow the removal of large areas of hair, veins or capillaries on almost any body area, such as on the face, arms, legs, breasts, hands, stomach and the like. Flashlamp treatment provides a low discomfort level to the patient, and hair removal may last for weeks on a body area. However, the current flashlamp methods used for hair removal sometimes produce unwanted side effects such as burning the skin, changes in skin pigmentation, and permanent scarring.

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Pulsed flashlamps emit filtered visible light having wavelengths in the range of 550nm and above, but have not been effective in providing permanent hair removal.

Current cutaneous flashlamps work by delivering energy in the form of visible light which is absorbed by the cutaneous target, heating the target and thereby causing its destruction. Different skin structures have different colors, different surface to volume configurations, and other factors which cause differential rates of heat loss. All of the hair removal flashlamps work by application of the principal of selective photothermolysis, i.e. selective destruction due to heat caused by absorption of light. Visible light, which has a varied wavelength, is absorbed by a target which has a complementary specific color for those wavelengths. This flashlamp target is called a chromophore. The usual chromophore for hair removal flashlamps is melanin, found in high concentration in brown and black hair, and is responsible for the color of hair.

The clinical problem is that melanin is also found in the epidermis, and is responsible for native skin color and tan. Flashlamp energy is therefore also absorbed into the epidermis. The problem of hair removal by flashlamps therefore is to deliver flashlamp energy that heats the hair to a sufficient degree to cause permanent damage and hair loss, yet spare the skin of any damage. Present flashlamp methods are unable to accomplish this.

The use of medical flashlamps to produce permanent hair removal in patients with hair of all colors, and skin of all colors, has, up to this time, been impossible to achieve with

current technology. While promising, the currently-used flashlamp methods have all had difficulty in treating patients with dark skin. In addition, even in Caucasian patients, the currently-used flashlamp methods have burned many patients, leading to prolonged changes in skin color and even, in some cases, to permanent scarring. Hair loss, although usually prolonged, has not been permanent for the majority of patients.

Nevertheless, the use of visible light in the range of 550nm to 900nm still appears to be an effective way to achieve long-term hair removal. To achieve predictable permanency we need to achieve higher temperatures in the hair without heating the epidermis to the point where it is burned. Current techniques are inadequate to accomplish this.

There remains a need for an improved flashlamp method which will supply a series of short flashlamp energy pulses with short time delays between pulses to heat a hair follicle sufficiently to cause permanent damage to that hair follicle, and yet spare the skin from burning, thus providing a safe and permanent method of hair removal.

A new flashlamp method has been developed that has the following major advantages: 1) increased efficacy, causing greater hair loss and true permanent hair removal; 2) increased safety, with burning of the skin eliminated, so that treatment has no side effects; and 3) it allows the use of flashlamp hair removal for

patients with dark skin, thereby greatly increasing the range of people who can be treated with this technology.

DESCRIPTION OF THE PRIOR ART

Flashlamp and laser methods for hair removal have been disclosed in the prior art. For example, U.S. Patent Nos. 5,630,811 and 5,658,323 to Miller disclose a method and apparatus for dermatology treatments for lesions and hair removal using a modified laser device. The specific target for the laser radiation is the melanin within the hair shaft and within the melanocytes lining of the follicular duct. Pulse width is controlled to provide a direct thermal effect from a single pulse.

U.S. Patent No. 5,647,866 to Zaias discloses a method of hair depilation through the application of pulsed laser energy having a wavelength readily absorbed by hemoglobin. The process of selective photothermolysis is used by the laser to focus on a particular region in the epidermis to be irradiated. The pulse duration or time period (30 to 40 nanoseconds) is shorter than the thermal relaxation time for melanin in hair.

U.S. Patent No. 5,683,380 to Eckhouse discloses a method and apparatus for removing hair (depilation) using a single high intensity pulsed flashlamp which emits a broad spectrum of pulsed incoherent light that is polychromatic. Because of the broad spectrum of wavelengths emitted by the flashlamp, only part of the

light energy is absorbed by the hair, making it inefficient for permanent hair removal, although it does provide temporary hair loss.

None of these prior art patents disclose the particular method of the present invention using a flashlamp for safe and permanent hair removal.

Accordingly, it is an object of the present invention to provide an improved flashlamp method which supplies a series of short pulses of flashlamp energy with short delays between the pulses from the flashlamp to heat a hair follicle and hair follicle shaft to cause permanent damage to that hair follicle and shaft, and yet spare the skin from burning, thus providing a safe and permanent method of hair removal.

Another object of the present invention is to provide an improved flashlamp method which sequentially emits a series of pulses of incoherent light energy for permanently removing a plurality of hair follicles, veins or capillaries from the skin area of a patient.

Another object of the present invention is to provide an improved flashlamp method for ease of use by the operator in directing the series of flashlamp pulses at the skin to rapidly remove large areas of hair on almost any body area, such as on the face, hands, arms, legs, breasts, stomach and the like, where such treatment provides a low discomfort level to the patient.

Another object of the present invention is to provide an improved flashlamp method for treatment of other cutaneous conditions (in addition to hair), such as the treatment of leg veins, spider veins, angiomas, lesions, other vascular anomalies and other dermatological conditions effecting the skin of a patient.

Another object of the present invention is to provide an improved flashlamp method for adjusting the number of pulses, the pulse width, the time delay between pulses, and the energy level of each pulse, to customize treatment and the energy delivered to the spot being treated according to skin color, hair color, hair diameter and the anatomic site being treated.

Another object of the present invention is to provide safe and permanent hair removal in a wider range of patients having hairs of all colors and skin of all colors, including patients with dark skin. Generally, the present invention will accommodate all persons having hair which is darker than their skin.

Another object of the present invention is to provide a delay between flashlamp pulses which is much shorter than the thermal relaxation time of the hair being treated, so the hair does not cool off between pulses.

Another object of the present invention is to provide a method wherein the delay between flashlamp pulses is so short that less energy has to be transmitted to the hair to cause permanent hair loss.

SUMMARY OF THE INVENTION

A method of removing hair or blood vessels from the skin of a patient using a flashlamp, a sequence control device and an optical delivery system, which includes the steps of controlling the flashlamp to sequentially emit a series of pulses of incoherent light energy, transmitting the series of pulses of incoherent light energy through the optical delivery system to the same spot on the skin of the patient, irradiating the same spot on the skin containing the hair or blood vessels with the sequential pulses of incoherent light energy transmitted through the optical delivery system from the flashlamp, and pulsing the flashlamp at least two or more times at a wavelength in the range of 550 to 1200nm, at a power level in the range of 4 to 25 Joules/cm², each pulse having a duration in the range of $\frac{1}{2}$ to 10 milliseconds with a preferred range of 1 to 8ms, a delay between pulses in the range of 1 to 10 milliseconds, and having a beam diameter on the treatment area in the range of 4 to 50 millimeters. The new method requires that a series of relatively low energy flashlamp pulses be delivered in rapid succession with short delays between pulses to exactly the same area of the skin, so that the hair does not have time to dissipate the heat between pulses. Relatively low energy is delivered to the hair germinative apparatus using a series of short pulses from the flashlamp, with the pulses repeated at short intervals so the hair does not have time to dissipate the heat energy between pulses. For most patients, this means five or less

low-energy (2 to 15 Joules/cm²) short duration (2 to 6 milliseconds) pulses, separated by short delays of less than 10 milliseconds, each with a large (e.g. 10 millimeters or greater) spot size. The short delay between pulses is shorter than the thermal relaxation time of the hair and skin being treated, so the hair does not cool off between the pulses.

BRIEF DESCRIPTION OF THE DRAWINGS

Further objects, features, and advantages of the present invention will become apparent upon consideration of the detailed description of the presently-preferred embodiments, when taken in conjunction with the accompanying drawings wherein:

Figure 1 is a perspective view of the flashlamp apparatus of the preferred embodiment of the present invention showing the control box housing having a control panel thereon, the flexible electrical cable, the flashlamp having a handpiece thereon with an operating pulse firing button, shown in an operational mode;

Figure 2 is an enlarged perspective view of the flashlamp apparatus of the present invention showing the flexible cable and the flashlamp handpiece having a pulse firing button thereon, shown in an operational mode;

Figure 3 is a cross-sectional view of a plurality of hair shafts within a region of skin tissue being irradiated with a flashlamp beam from the flashlamp handpiece of the present invention;

Figure 4 is a cross-sectional view of a plurality of hair shafts within a region of skin tissue after irradiation by a flashlamp according to the present invention and showing the gradual atrophy of the hair follicle region;

5 Figure 5A is a graph showing the time profile and the optical intensity field performance for the prior art flashlamp used during the hair removal process for fair skin and light hair patient treatments;

10 Figure 5B is a graph showing the time profile and the optical intensity field performance for the prior art flashlamp used during the hair removal process for dark skin and dark hair patient treatments ;

15 Figure 5C is a graph showing the time profile and the optical intensity field performance for the sequential pulsing of coherent light energy using a single flashlamp for the hair removal process and treatment of Caucasian patients with fair skin and light hair;

20 Figure 5D is a graph showing the time profile and the optical intensity field performance for the sequential pulsing of coherent light energy using a single flashlamp for the hair removal process and treatment of Caucasian patients with fair skin and dark hair;

 Figure 5E is a graph showing the time profile and the optical intensity field performance for the sequential pulsing of coherent light energy using a single flashlamp for the hair removal process and treatment of patients with olive skin and dark hair; and

Figure 5F is a graph showing the time profile and the optical intensity field performance for the sequential pulsing of coherent light energy of a single flashlamp for the hair removal process and treatment of African-American patients with dark skin and dark hair.

DETAILED DESCRIPTION OF
THE PREFERRED EMBODIMENT

The flashlamp apparatus 10 and the improved method for permanently removing a plurality of hair follicles 20 from a patient's skin area 14, or for removing blood vessels 28 such as veins and capillaries, are represented in detail by Figures 1 and 2 through 5C to 5F.

Figures 5A and 5B show the methods of prior art flashlamps in use with fair skin, light hair patients, and with dark skin, dark hair patients, respectively. Figure 5A shows two (2) pulses of 4ms each with a time delay of 10ms for treating fair skin and light hair. In this case, the prior art method uses a pulse delay of 10ms which is too long and allows the hair to cool too much between pulses. As a result, the hair does not reach a high enough temperature to be destroyed by the second pulse. Figure 5B shows three (3) pulses of 3.6ms with two (2) time delays of 40ms each. Again, in this prior art method, the pulse delays are too long and allow the hair to cool too much between pulses. As a result, the hair does not reach a high enough temperature to be destroyed by this sequence of pulses.

The flashlamp apparatus 10 shown in Figures 1 and 2 of the drawings, includes a control box 40 connected to a flashlamp device 70 via electrical cable 50, a computer 90, a capacitor member 100 for discharging the flashlamp light pulses 74, an electrical panel box 160 having electrical circuitry therein, and a power source 170. Electrical cable 50 is connected to a flashlamp handpiece 110 having a pulse firing button 118 thereon. Control box housing 40 includes a flashlamp programmable control panel 120 thereon.

Flashlamp device 70, as shown in Figure 1, includes a flashlamp projector lens 72 of a specific wavelength for producing an incoherent flashlamp beam 74 having a flashlamp beam diameter 75 of a given width. The electrical cable 50 transmits pulses of coherent light energy (flashlamp beam 74) through the lens 72. Flashlamp device 70 is electrically connected to the computer 90, to the flashlamp programmable control panel 120, and to the electrical panel box 160.

The flashlamp device 70 is adjustable to control the energy level (Joules/cm²), pulse width duration (ms), delay time between pulses (ms), spot size (mm) and wavelength (nm) via the flashlamp programmable control panel 120. The most effective wavelengths for permanent hair removal are in the range of 550nm to 900nm when using the flashlamp.

The computer 90 is used for controlling the sequential pulsing of the flashlamp beam 74 from flashlamp device 70, and includes a micro-controller module 92 for controlling the flashlamp 70 to

sequentially emit a series of pulses of coherent light energy via capacitor member 100 when the flashlamp operator depresses the pulse firing button 118 on flashlamp handpiece 110. The micro-controller module 92 may be in the form of a microprocessor or an electronic timing device. The series of pulsed flashlamp beams 74 will destroy and permanently remove the plurality of hair follicles 20 from the skin area 14 of a patient, as shown in Figures 2 to 4 of the drawings.

The optical delivery system includes the flashlamp handpiece 110 used for delivering and emitting the series of sequential flashlamp pulses 74 from flashlamp device 70, via the micro-controller module 92 of computer 90. Flashlamp handpiece 110 includes a flashlamp dispersal member 112 having a flashlamp portal opening 114 for receiving electrical cable 50 and lens 72 for emitting the flashlamp pulses 74 of flashlamp device 70. Flashlamp handpiece 110 further includes a hand gripping/holding section 116 having a pulse firing button 118 thereon. Pulse firing button 118 is electrically connected to the micro-controller module 92 of computer 90.

The flashlamp programmable control panel 120 is used for controlling the various output functions of energy/power level, in Joules/centimeters² (J/cm²), the irradiation pulse width duration in milliseconds (ms), the pulse delay in milliseconds (ms), the number of pulses, and the flashlamp beam diameter in millimeters (mm) for the single flashlamp device 70. Control panel 120

includes a plurality of control members 122 to 130 and a visual display screen 132 having a keyboard 134 for programming the aforementioned output functions of energy/power level, pulse width duration, pulse delay, the number of pulses, and flashlamp beam diameter 75. The control panel 120 includes an ON/OFF button 122 for activating and de-activating the flashlamp device 70; a control knob/selector 124 for adjusting the energy/power level of the flashlamp device 70; a control knob/selector 126 for adjusting the irradiation pulse width duration (ms) of flashlamp beam 74 of the flashlamp device 70; a control knob/selector 128 for adjusting the pulse delay of the de-activation time (ms) of flashlamp beam 74 of the flashlamp device 70; and a control knob/selector 130 for adjusting the flashlamp beam diameter 75 of the flashlamp device 70. Control panel 120 is electrically connected to flashlamp device 70 via electrical line 50, as shown in Figure 1.

METHOD OF THE PRESENT INVENTION

As depicted in Figure 3, the plurality of hair shafts 12 project below the epidermis region 16 of skin area 14 and into the dermis region 18. Each hair shaft 12 extends down the follicle 20 and includes a sebaceous gland 22 and which at the anagen stage of the hair cycle further includes a follicular papilla 24 within the hair bulb 26 of hair shaft 12. The follicular papilla 24 is supplied with a plurality of small blood vessels 28 that provide

the plurality of growing hair shafts 12 with nourishment. The follicular papilla 24 is an essential structure within the follicle matrix structure 30.

In order to assure destruction of the follicular papilla 24 and permanent hair removal, a sufficient flashlamp energy level is required that destroys the hair but does not burn the skin. In addition, the depth of penetration of the series of flashlamp pulses 74 must be sufficient to cause permanent removal of hair shaft 12 from the epidermis and dermis regions 16 and 18 of the patient's skin area 14.

The flashlamp method of the present invention provides short pulse delays of between 1ms to 10ms between pulses, with a preferred pulse delay time of less than 8ms. The single flashlamp has the capability of sequentially emitting a series of pulses two (2) to six (6) times on the same spot of the patient's skin 14. For example, three (3) pulses may be emitted at 10 Joules/cm² per pulse each having a pulse width of 2.5ms and a delay time between the pulses of 8ms which allows the delivery of 30 Joules/cm² to the same spot in 23.5ms. Various Examples C through F are shown in Figures 5C to 5F, respectively, of the drawings.

As shown in Figures 2 and 3 of the drawings, the flashlamp operator (not shown) positions the flashlamp dispersal member 112 of the flashlamp handpiece 110 over a selected treatment area, such as the navel area 34 of the stomach 32 of the patient being treated. The flashlamp dispersal member 112 is positioned, as

shown in Figure 3, by the hand 36 of the flashlamp operator such that the series of flashlamp pulses 74 are substantially perpendicular over the selected treatment area, such as a plurality of hair follicles 20 to be removed. Handpiece dispersal member 112 is positioned through a gel compound 13 on the skin 14 at a location (hair that is to be removed) for directing the series of flashlamp pulses 74 to strike the plurality of follicular papilla 24 in order to irradiate them in a proper mode. While the handpiece dispersal member 112 is maintained perpendicular to the skin 14 and on the gel compound 13, it is moved parallel to the plane of the skin and along the surface of the skin area 14 for irradiating successive pluralities of hair follicles 20. The handpiece 110 is then moved vertically to the next horizontal line to repeat the removal procedure. The critical regions of the hair follicle matrix structure 30 include hair follicles 20, sebaceous glands 22 and follicular papillas 24 which are irradiated such that the series of pulsed flashlamp beams 74 can be moved across the skin area 14 or otherwise moved over a large are of skin to be treated.

Application of the series of flashlamp pulses 74 to the plurality of hair follicles 20 and to the plurality of follicular papillas 24 causes selective photothermolysis of the hair germinative apparatus, and more particularly, disruption of the hair follicle matrix structure 30 including vaporization of the deposited melanin, capillary destruction of the papillas 24, as

well as vacuolation, edema, gas bubbles and protein denaturation. When the flashlamp pulses 74 applied to the plurality of hair follicles 20 are of sufficient level, these effects will seriously injure each of the hair follicles 20 and papillas 24 being irradiated thereby permanently damaging the hair germ 26 which is responsible for hair regrowth which results in permanent hair removal. The initial flashlamp pulse 74 of flashlamp device 70 heats up the hair follicles 20 and subsequent flashlamp pulses 74 supply further heat energy to vaporize the hair follicles 20, as depicted in Figures 3 and 4 of the drawings. This sequential pulsing of flashlamp pulses 74 two (2) to six (6) times per treatment cycle allows the hair temperature of follicles 20 to increase from room temperature of 38°C to well over 100°C for the vaporization of the hair follicles 20.

An improved flashlamp method has been provided which, by dividing the flashlamp energy delivery into multiple, individually adjustable pulses, with an adjustable short delay between the pulses, allows it to achieve permanent hair removal without burning the skin on both light and dark skinned patients having either fine or coarse hair. The pulse repetition rate (the delay between pulses) is less than the thermal relaxation time (TRT) of the hair and skin being treated, so that the hair does not have time to dissipate its heat and cool down between pulses. This flashlamp method provides for 1) adjusting the pulse width, the number of pulses, and fluence of the flashlamp; 2) an improved optical

delivery system, so that each fired pulse is delivered to precisely the same spot; 3) the operator to precisely define the delay between pulses, and adjust this delay according to clinical variables, such as skin color, hair color, and hair coarseness; and 4) the delivery of these pulses much more rapidly than previous single long pulse flashlamps of the prior art, so that the delay between pulses is less than the TRT of the patient's hair and skin. Treatment may therefore be customized according to skin color, hair color, hair diameter, and the anatomic site being treated, as depicted by Examples C, D, E and F of Figures 5C, 5D, 5E and 5F, respectively.

The improved method requires that a series of relatively low energy flashlamp pulses be delivered in rapid succession with short delays between pulses, to exactly the same area of the skin. Relatively low energy is delivered to the hair germinative apparatus using a series of short pulses from the single flashlamp, with the pulses repeated at short intervals so that the hair does not have time to dissipate the heat energy between pulses. For most patients, this means five or less low-energy (2 to 20 Joules/cm²) short duration (2 to 6 milliseconds) pulses, separated by short delays of less than 10 milliseconds, each with a large (e.g., 10 millimeters or greater) spot size. The short delay between pulses is shorter than the thermal relaxation time of the hair being treated, so the hair does not cool off between the pulses.

The clinical circumstances which the flashlamp operator encounters include situations where the characteristics of the flashlamp energy delivered must be dramatically changed in order to deliver enough energy without skin damage to permanently remove the hair. The reason for this is that many variables affect the way flashlamp energy is absorbed. For instance, dark hair absorbs more flashlamp energy than light hair, as does dark skin. Coarse hair retains the heat caused by absorption of flashlamp energy longer than fine hair, and skin cools faster than hair. By taking advantage of these differential rates of heating and cooling one can fashion a series of flashlamp energy pulses that will selectively and permanently remove hair.

For example, an African-American patient with brown skin and coarse, black hair would need to have the energy delivered more slowly with a longer delay between pulses than a Caucasian patient. The delay between pulses is selected to be much less than the TRT of the hair. Successive pulses are then emitted, each one heating the hair more, until permanent destruction of the hair is caused. The skin heats up, but not enough to cause damage. As shown by Example F of Figure 5F, the patient receives three (3) pulses of 2.5 milliseconds each at a energy level of 10 Joules/cm² each. The time delay between pulses is relatively long (e.g. 8ms), and the total cycle is 23.5 milliseconds. Thus, 30 Joules/cm² is delivered safely to a patient in whom 30 Joules/cm² delivered in a single pulse might burn the skin.

In another example, a patient with olive dark skin would need to have the energy delivered more slowly with a longer delay between pulses than a Caucasian patient. The delay between pulses is selected to be much less than the TRT of the hair. Successive
5 pulses are then emitted, each one heating the hair more, until permanent destruction of the hair is caused. The skin heats up, but not enough to cause damage. As shown by Example E of Figure 5E, the patient receives three (3) pulses of 2.7 milliseconds, each at a energy level of 11 Joules/cm² each. The time delay between
10 pulses is relatively long (e.g. 6 ms), and the total cycle is 20.1 milliseconds. Thus, 33 Joules/cm² is delivered safely to a patient in whom 33 Joules/cm² delivered in a single pulse might burn the skin.

A Caucasian patient with light brown, fine hair, and light,
15 untanned skin requires more energy delivered in order to achieve permanent hair removal. Light, fine hair absorbs little flashlamp energy, but even light skin will absorb some flashlamp energy, which is why pulsed energy delivery, with a delay to allow skin cooling, allows the delivery of more flashlamp energy, safely, to
20 the hair germinative apparatus. In this situation, as shown by Example C of Figure 5C, the patient receives two (2) pulses of 3.8 milliseconds, each at a energy level of 19 Joules/cm² each. The time delay between pulses is short (e.g. 1ms) since light skin

cools faster. Thus, 38 Joules/cm² are thereby delivered safely in two (2) pulses over a 8.6 milliseconds cycle to a patient in whom 38 Joules/cm² delivered in a single pulse might burn the skin.

5 A Caucasian patient with dark black, fine hair, and light, untanned skin requires more energy delivered in order to achieve permanent hair removal. Dark, fine hair absorbs some flashlamp energy, but even light skin will absorb some flashlamp energy, which is why pulsed energy delivery, with a delay to allow skin cooling, allows the delivery of more flashlamp energy, safely, to the hair germinative apparatus. In this situation, as shown by Example D of Figure 5D, the patient receives two (2) pulses of 3.8 milliseconds, each at a energy level of 18 Joules/cm² each. The time delay between pulses is relatively short (e.g. 3ms) since light skin cools faster. Thus, 36 Joules/cm² are thereby delivered safely in two (2) pulses over a 10.6 milliseconds cycle to a patient in whom 36 Joules/cm² delivered in a single pulse might burn the skin.

20 The actual irradiating of the plurality of hair follicles is accomplished by the flashlamp operator depressing the pulse firing button 118 of flashlamp handpiece 110 which in turn emits a series of flashlamp pulses 74 in a sequenced pulsed cycle over the designated treatment area 30, as shown in Figures 2, 3 and 5C to 5F of the drawings. In the foregoing examples, a series of flashlamp pulses 74 of single flashlamp device 70 are sequentially pulsed for

an irradiation time of preferably 2 to 6 milliseconds (ms) per pulse (irradiation time can be varied in the range of $\frac{1}{2}$ to 10 milliseconds for each of the flashlamp pulses 74), with a pulse delay duration time between pulses of preferably 1 to 8 milliseconds (pulse delay duration time can be varied in the range of 1 to 10 milliseconds (ms) for each of the flashlamp pulses 74 of flashlamp device 70 being pulsed onto the skin of the patient). A series of sequential irradiation pulses may be emitted two (2) to six (6) times for a complete treatment cycle, as shown in the Examples, which is sufficient to permanently remove the plurality of hair follicles 20 of the patient's skin area 14 being treated.

In the specific Example C of a two (2) pulse cycle, as shown in detail by Figure 5C, flashlamp 70 is controlled by sequence control device 90 so that flashlamp 70 emits a 3.8ms pulse at an energy level of 19 Joules/cm², then there is a 1ms delay, and then flashlamp 70 emits another sequential 3.8ms pulse at an energy level of 19 Joules/cm² to the same spot. This short delay between pulses is enough time to allow the skin being treated to slightly cool the skin 14 so that it can receive the energy (e.g. 38 Joules/cm²) safely without burning the skin and permanently remove the hair in a cycle time of 8.6 milliseconds. In addition, the 38 Joules/cm² is enough energy to burn the hair follicles over a larger spot size so that a larger area of the patient can be treated in substantially less time. Spot size 75 may be circular

or rectangular and a grid pattern may be used for ease of moving handpiece assembly 110 across the patient's skin 14.

Another treatment cycle for permanently removing hair follicles 20 using a flashlamp 70 would have the flashlamp operator pulsing the flashlamp pulses 74 at an energy level of 7.5 Joules/cm² per pulse with an irradiation pulse duration of 4ms per pulse for a series of four (4) pulses. The time delay between each of the 4 pulses would be 5ms so there would be three (3) time delays between the four (4) irradiation pulses. The complete treatment cycle includes pulsed irradiation time (4 x 4ms) of 16ms plus three (3) time delay segments (3 x 5ms) of 15ms for a total treatment cycle time (16ms + 15ms) of 31ms at a total energy level of 30 Joules/cm² (4 pulses x 7.5 Joules/cm² per pulse). This treatment cycle is sufficient to safely and permanently remove the plurality of hair follicles 20 being treated by flashlamp pulses 74 of the flashlamp apparatus 10.

In another example, the flashlamp operator may want flashlamp device 70 to operate and emit a series of pulses of flashlamp beams 74 sequentially at different pulse durations of 5ms, 4ms, and 3ms with different delay times of 6ms and 5ms between the pulses, at an energy level of 10 Joules/cm² per pulse, with a flashlamp beam diameter 75 of 10 millimeters. For this specific treatment cycle the operator would program the above data into the programmable control panel 120, as shown in Figure 5B of the drawings, in the following manner. The flashlamp operator initiates the programming

of this specific treatment cycle by turning ON the control panel 120 via ON/OFF button 122. The operator then selects and activates the control knob 124 for adjusting the power level to 10 Joules/cm² for flashlamp device 70, and then the operator keys in the 10 Joules/cm² via keyboard 134 for each of the 5ms, 4ms and 3ms pulses and this data is then visually displayed on display screen 132. If the power level for each pulse duration is correct the operator presses the "ENTER" key on keyboard 134 in order to enter the data in control panel 120. Next, the flashlamp operator then selects and activates the control knob 130 for adjusting the flashlamp beam diameter 75 of flashlamp device 70 to be a 10 millimeter diameter.

Then the operator keys in the 10 millimeters for flashlamp beam diameter 75 via keyboard 134 for each of the 5ms, 4ms and 3ms pulses, and this data is then visually displayed on display screen 132. If the flashlamp beam diameter 75 for each pulse duration is correct the operator presses the "ENTER" key on keyboard 134 in order to enter this data in control panel 120. The next step of programming by the flashlamp operator is the selection and activation of the control knob 126 for pulse duration of flashlamp 70, at which time the operator then keys in the aforementioned data/information via keyboard 134 so that the first pulse duration is 5ms, the second pulse duration is 4ms and the third pulse duration is 3ms, and it is then visually displayed on display screen 132. If the series of pulse durations are correct the

operator presses the "ENTER" key on keyboard 134 to enter the above data into the programmable control panel 120. The last step of programming by the flashlamp operator is the selection and activation of the control knob 128 for pulse delay time between irradiation pulses of flashlamp device 70, at which time the operator then keys in the aforementioned information via keyboard 134 so that the first pulse delay time of 6ms is between the pulses of 5ms and 4ms, and the second delay time of 5ms is between the pulses of 4ms and 3ms, and it is then visually displayed on display screen 132. If the series of time delays between pulses are correct, the operator presses the "ENTER" key on keyboard 134 to enter the above information/data in the programmable control panel 120.

Flashlamp apparatus 10 is now ready to fire the series of flashlamp pulses 74 as programmed. Flashlamp operator depresses the pulse firing button 118 over the selected treatment area 34 to start the pulsed treatment cycle. There is a first pulse irradiation time of 5ms followed by a first time delay of 6ms, sequentially followed by a second pulse irradiation time of 4ms followed by a second time delay of 5ms, and sequentially followed by a third pulse irradiation time of 3ms. The complete treatment cycle of pulsed irradiation and delay times is thus 23 milliseconds at a total energy level of 30 Joules/cm^2 (three (3) pulses at 10 Joules/cm^2 per pulse) which is sufficient to permanently remove the plurality of hair follicles 20 of the patient's skin area 14 being

treated by flashlamp beams 74 of flashlamp apparatus 10, as shown in Figure 3 of the drawings.

As shown in Figure 4, the flashlamp-damaged follicles 20 will gradually recede due to destruction of the follicle matrix structure 30, including disruption of blood flow from the blood vessel capillaries 28 to each of the papillas 24. The hair follicles 20 show gradual atrophy without a blood supply thereby causing permanent hair removal.

Different types of hair and skin pigmentation, different cooling times of the epidermis, and hair follicles of different sizes, as well as the location of body hair to be removed will require different sequences of flashlamp treatment to fit the individual needs of the patient undergoing the therapeutic flashlamp treatment for permanent hair removal. This flashlamp treatment of sequential flashlamp pulses 74 allows the flashlamp operator to individually adjust each of the output functions of energy/power level, pulse width duration, number of pulses, pulse delay and flashlamp beam diameter 75 for the particular patient by using control panel 120 which controls the single flashlamp device 70 of flashlamp apparatus 10 of the present invention.

ADVANTAGES OF THE PRESENT INVENTION

Accordingly, an advantage of the present invention is that it provides an improved flashlamp method which supplies a series of short pulses of flashlamp energy with short delays between the

pulses from the flashlamp to heat a hair follicle and hair follicle shaft to cause permanent damage to that hair follicle and shaft, and yet spare the skin from burning, thus providing a safe and permanent method of hair removal.

5 Another advantage of the present invention is that it provides for an improved flashlamp method which sequentially emits a series of pulses of incoherent light energy for permanently removing a plurality of hair follicles, veins or capillaries from the skin area of a patient.

10 Another advantage of the present invention is that it provides for an improved flashlamp method for ease of use by the operator in directing the series of flashlamp pulses at the skin to rapidly remove large areas of hair on almost any body area, such as on the face, hands, arms, legs, breasts, stomach and the like, where such
15 treatment provides a low discomfort level to the patient.

20 Another advantage of the present invention is that it provides for an improved flashlamp method for treatment of other cutaneous conditions (in addition to hair), such as the treatment of leg veins, spider veins, angiomas, lesions, other vascular anomalies and other dermatological conditions effecting the skin of a patient.

25 Another advantage of the present invention is that it provides for an improved flashlamp method for adjusting the number of pulses, pulse width, the time delay between pulses, and the energy level of each pulse, to customize treatment and the energy

delivered to the spot being treated according to skin color, hair color, hair diameter and the anatomic site being treated.

Another advantage of the present invention is that it provides safe and permanent hair removal in a wider range of patients having hairs of all colors and skin of all colors, including patients with dark skin. Generally, the present invention will accommodate all persons having hair which is darker than their skin.

Another advantage of the present invention is that it provides a delay between flashlamp pulses which is much shorter than the thermal relaxation time of the hair being treated, so the hair does not cool off between pulses.

Another advantage of the present invention is that it provides a method wherein the delay between flashlamp pulses is so short that less energy has to be transmitted to the hair to cause permanent hair loss.

A latitude of modification, change, and substitution is intended in the foregoing disclosure, and in some instances, some features of the invention will be employed without a corresponding use of other features. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the spirit and scope of the invention herein.

WHAT IS CLAIMED IS:

1. A method of removing hair or blood vessels from the skin of a patient using a flashlamp apparatus having a flashlamp, a sequence control device and an optical delivery system, comprising
5 the steps of:

a) controlling said flashlamp to sequentially emit a series of pulses of incoherent light energy, each having a pulse width in the range of $\frac{1}{2}$ ms to 10ms;

10 b) transmitting said series of pulses of incoherent light energy through said optical delivery system to the same spot on the skin of the patient;

15 c) irradiating the same spot on the skin containing the hair or blood vessels with said series of sequential pulses of incoherent light energy transmitted through said optical delivery system from said flashlamp; and

20 d) pulsing said flashlamp at least two times through said optical delivery system at a wavelength in the range of 550 to 1200nm, at a power level in the range of 4 to 25 Joules/cm², each pulse having a duration in the range of $\frac{1}{2}$ to 10 milliseconds, a delay between pulses in the range of 1 to 10 milliseconds, and having a beam diameter on the treatment area in the range of 4 to 50 millimeters.

2. A method of removing hair or blood vessels from the skin of a patient using a flashlamp apparatus having a flashlamp, a sequence control device and an optical delivery system, comprising the steps of:

5 a) controlling said flashlamp to sequentially emit a series of pulses of incoherent light energy, each having a pulse width in the range of $\frac{1}{2}$ ms to 10ms;

10 b) transmitting said series of pulses of incoherent light energy through said optical delivery system to the same spot on the skin of the patient;

15 c) irradiating the same spot on the skin containing the hair or blood vessels with said series of sequential pulses of incoherent light energy transmitted through said optical delivery system from said flashlamp; and

20 d) pulsing said flashlamp to have a pulse delay between each of said pulses less than the thermal relaxation time (TRT) of the patient's hair and skin in order to remove the patient's hair and in order to avoid burning of the patient's skin, said pulse delay between each of said pulses being less than 10ms.

23 3. A method of removing hair in accordance with Claim 2, wherein said pulse width has a range of 2 to 6 milliseconds, in duration.

4. A method of removing hair in accordance with Claim 2,
wherein said delay between pulses has a range of 1 to 8
milliseconds in duration.

5. A method of removing hair in accordance with Claim 2,
wherein said power level has a range of 4 to 25 Joules/cm² per
pulse.

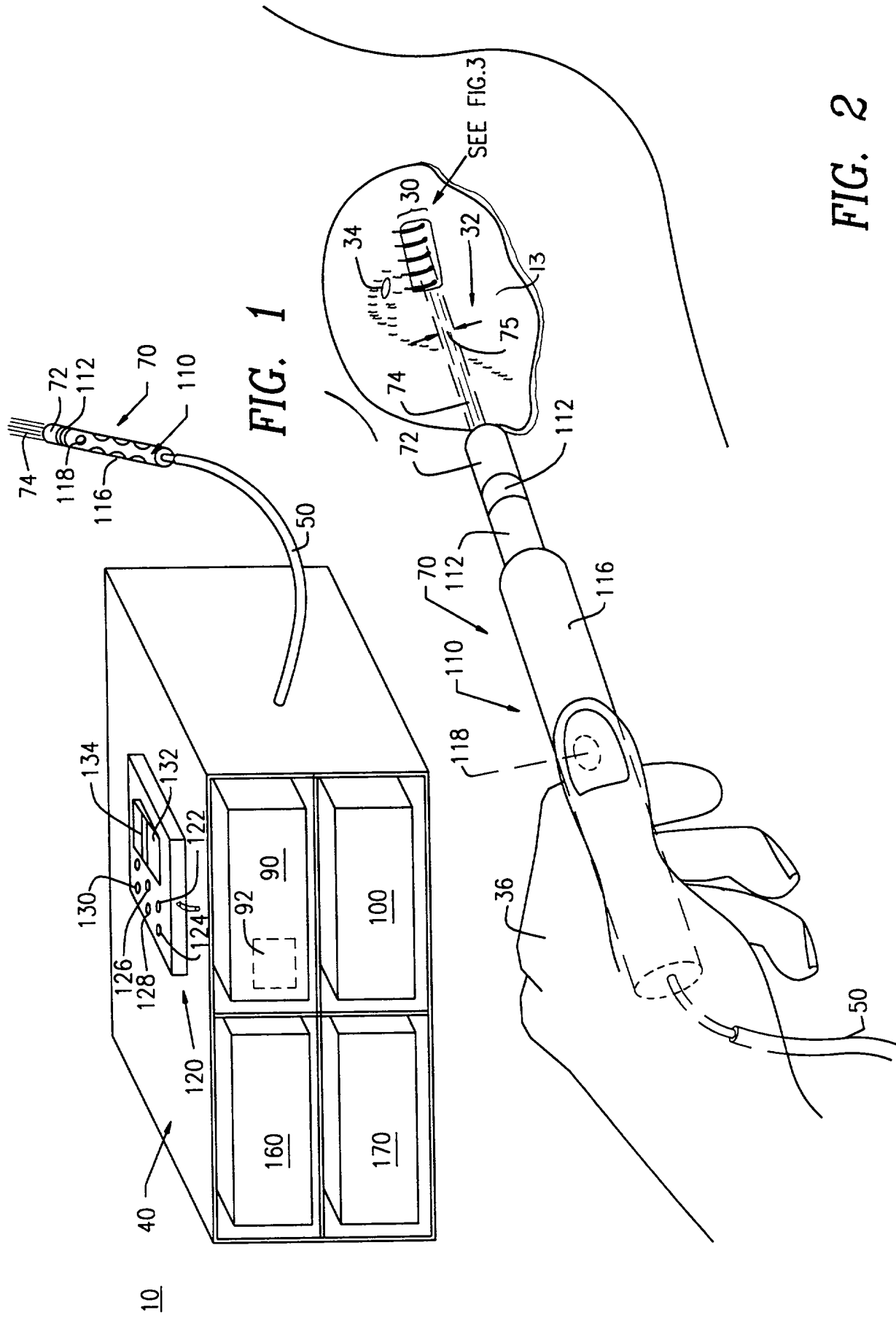
6. A method of removing hair in accordance with Claim 2,
wherein said beam diameter has a range of 4 to 50 millimeters.

7. A method of removing hair in accordance with Claim 2,
wherein said delay between pulses has a range of 2 to 4
milliseconds in duration for a sequence of two pulses.

8. A method of removing hair in accordance with Claim 2,
wherein said delay between pulses has a range of 3 to 6
milliseconds in duration for a sequence of three pulses.

ABSTRACT OF THE DISCLOSURE

A method of removing hair or blood vessels from the skin of a patient using a flashlamp, a sequence control device and an optical delivery system, and includes the steps of controlling the flashlamp to sequentially emit a series of pulses of incoherent light energy, transmitting the series of pulses of incoherent light energy through the optical delivery system to the same spot on the skin of the patient, irradiating the same spot on the skin containing the hair or blood vessels with the sequential pulses of incoherent light energy transmitted through the optical delivery system from the flashlamp, and pulsing the flashlamp at least two times at a wavelength in the range of 550 to 1200nm, at a power level in the range of 4 to 25 Joules/cm², each pulse having a duration in the range of ½ to 10 milliseconds, a delay between pulses in the range of 1 to 10 milliseconds, and having a beam diameter on the treatment area in the range of 4 to 50 millimeters.



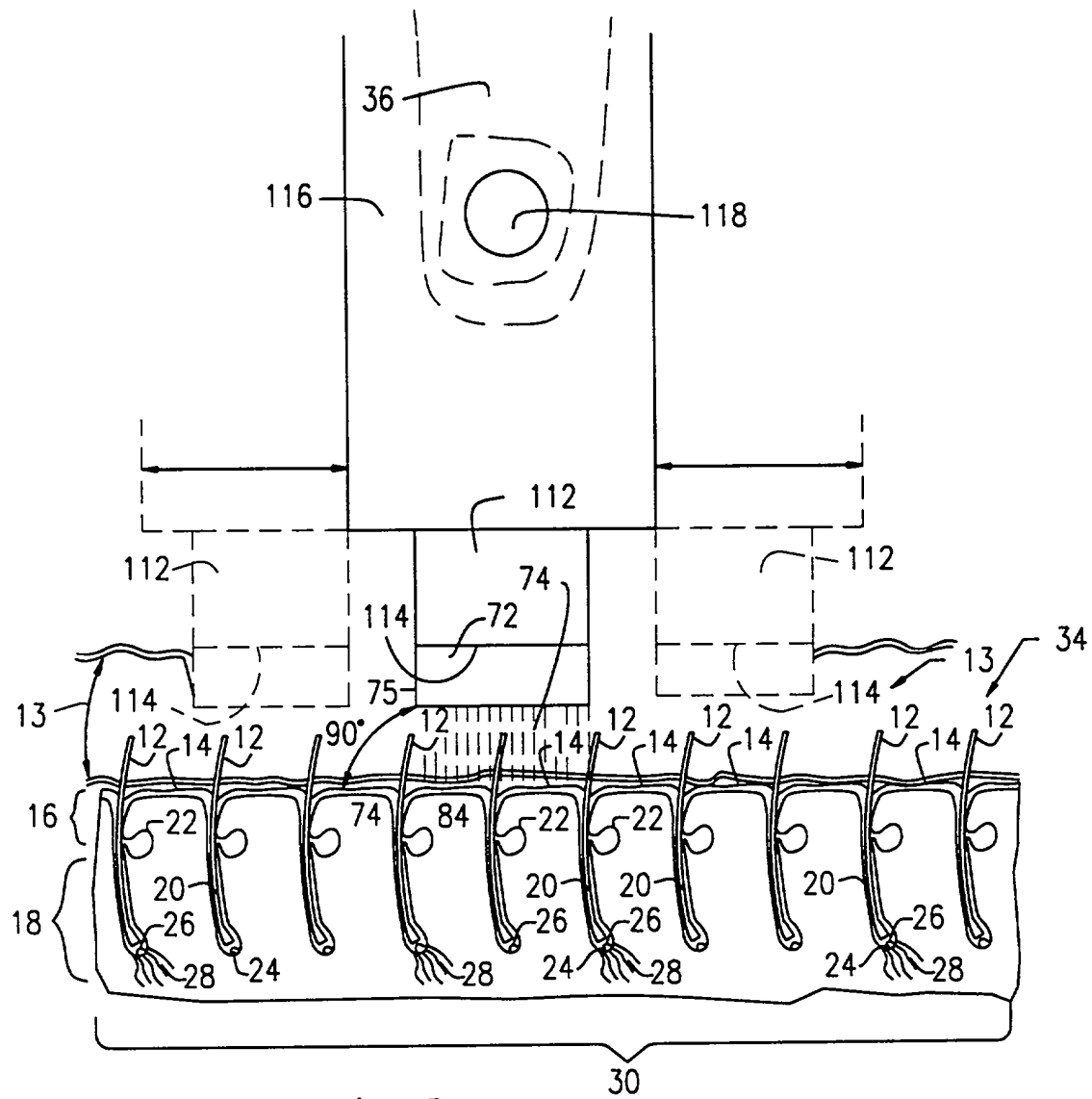


FIG. 3

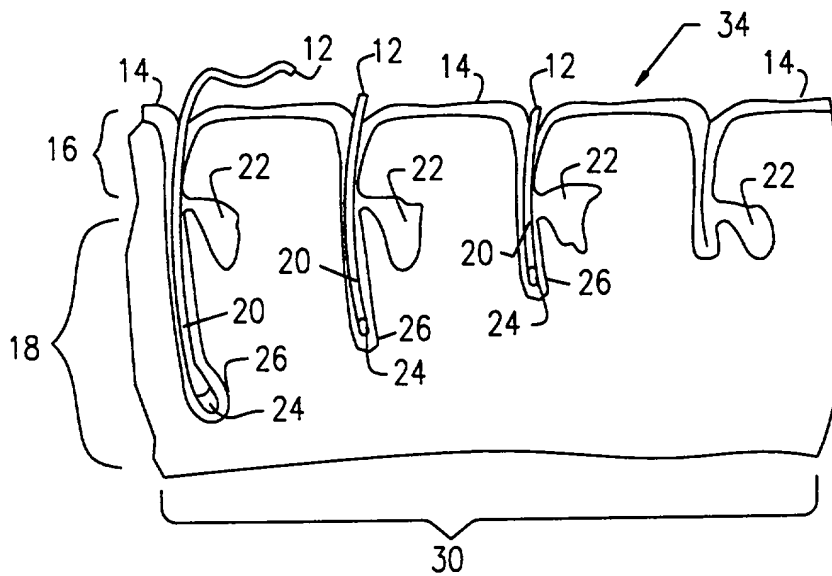


FIG. 4

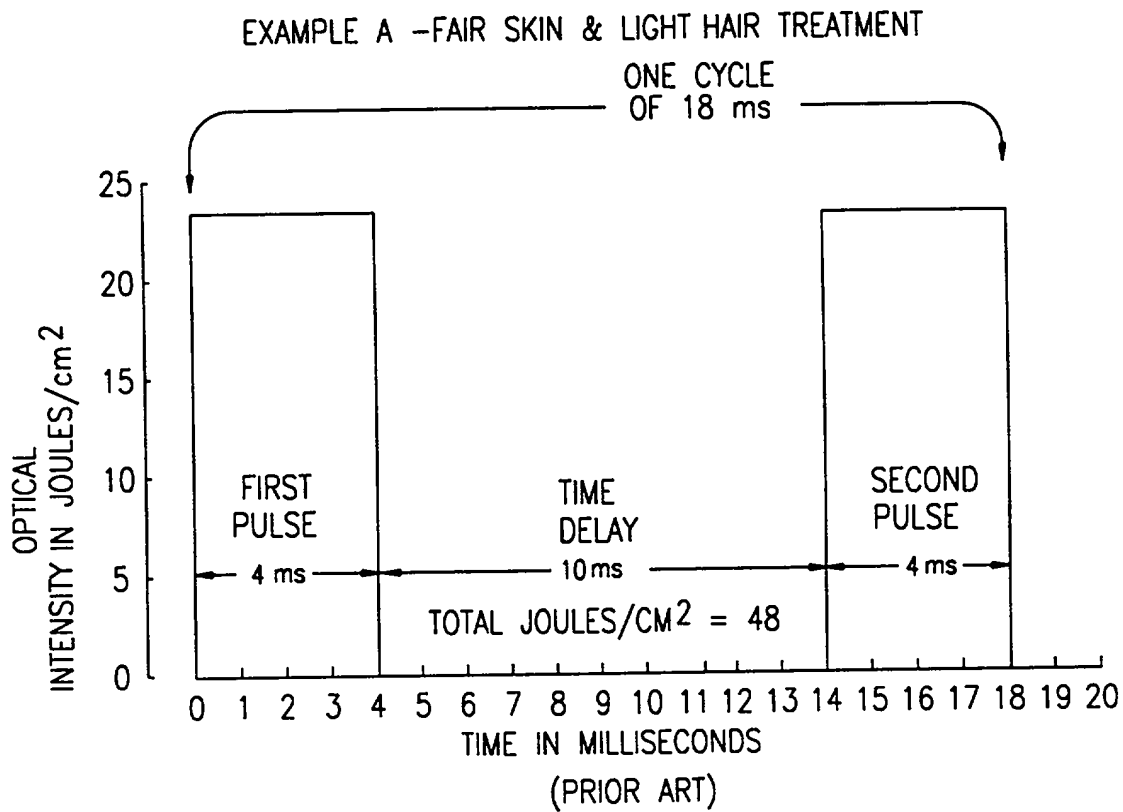


FIG. 5A

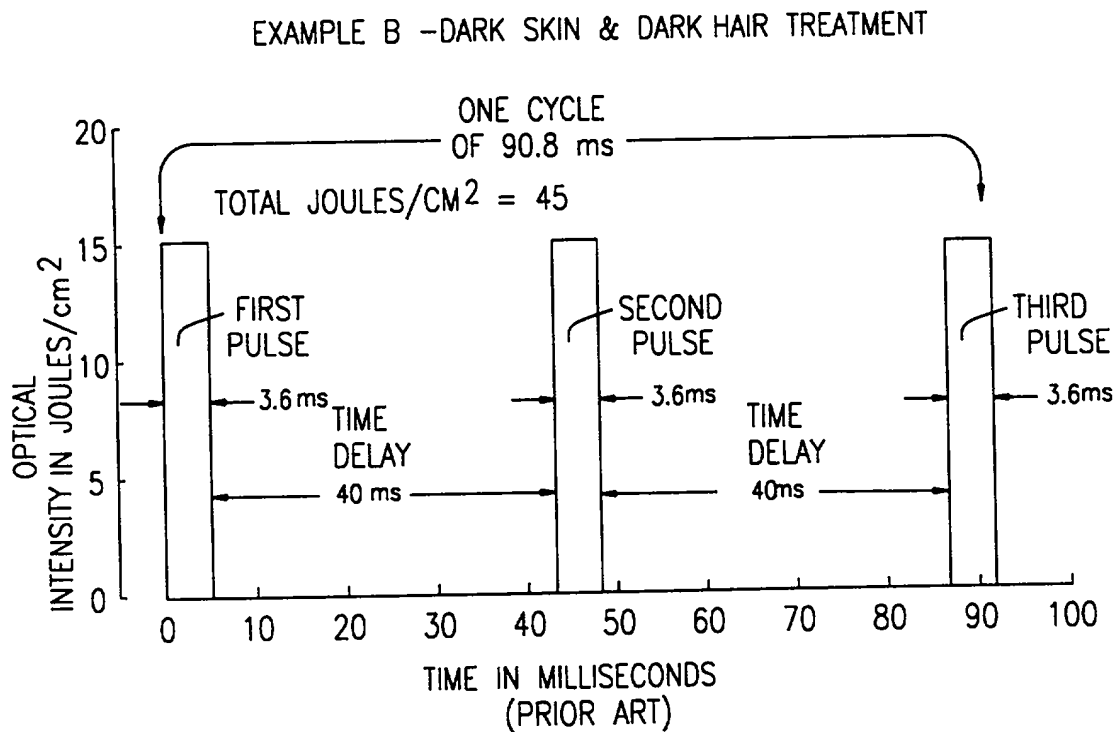
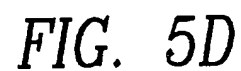
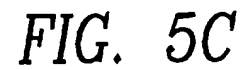


FIG. 5B

[illegible]

EXAMPLE E - OLIVE SKIN & DARK HAIR TREATMENT

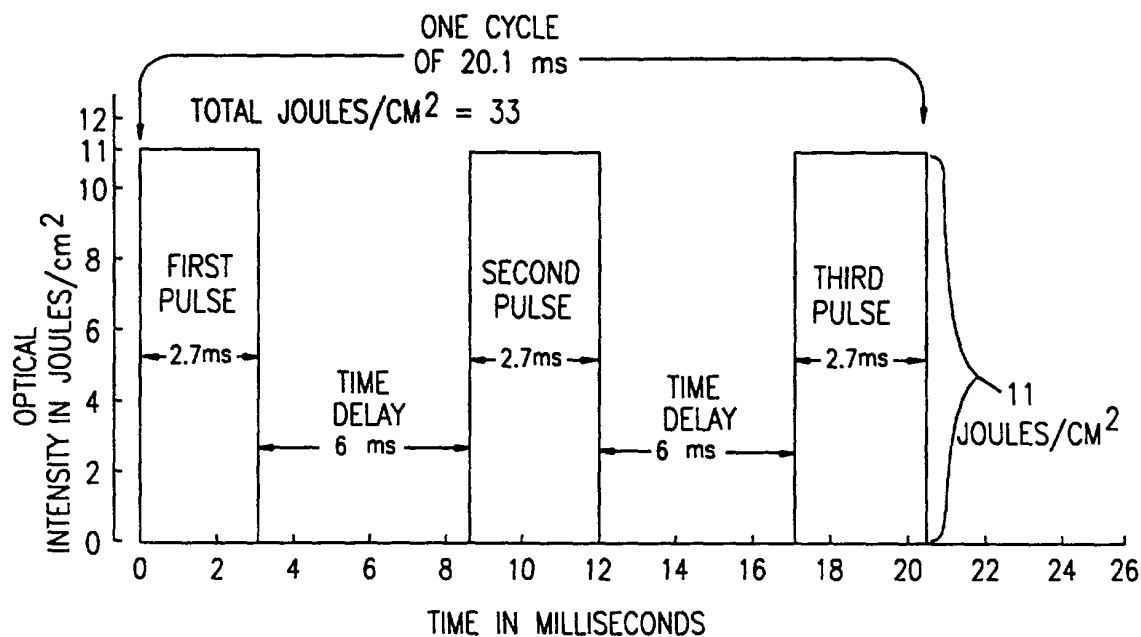


FIG. 5E

EXAMPLE F - DARK SKIN & DARK HAIR TREATMENT AFRICAN AMERICAN

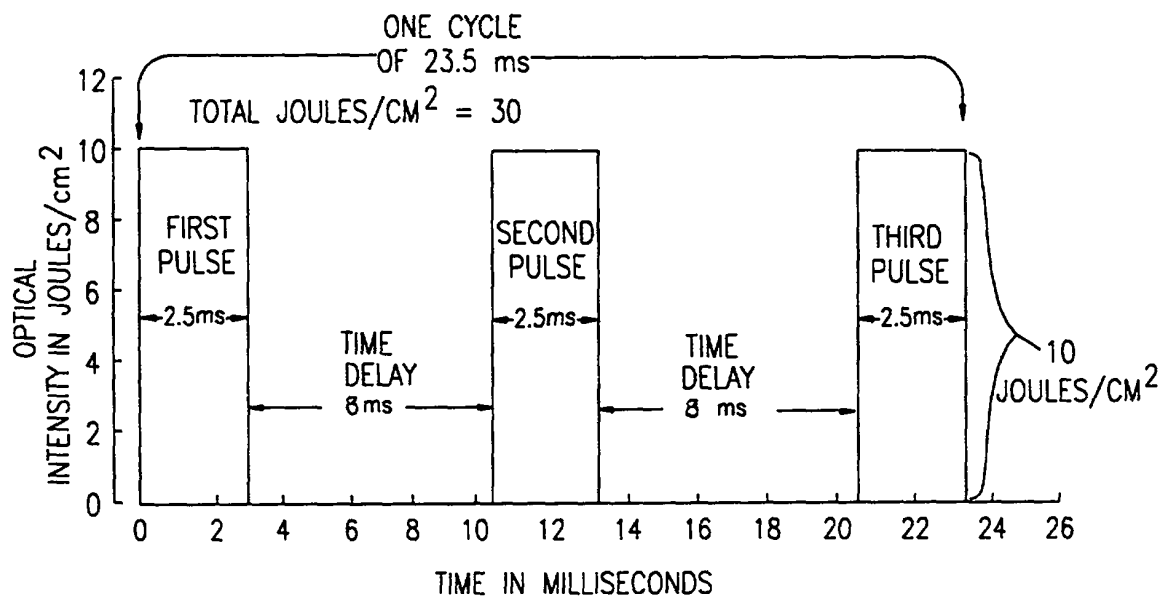


FIG. 5F

DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK 3.0-006

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD OF EMPLOYING A FLASHLAMP FOR REMOVAL OF HAIR, VEINS AND CAPILLARIES, the specification of which

(check one) ☒ is attached hereto.☐ was filed on _____ as

Application Serial No. _____ (if applicable).

and was amended on _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770Address all telephone calls to _____ at telephone no. (732) 634-3520

Address all correspondence to _____

EZRA SUTTON, P.A.Plaza 9, 900 Route 9Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor DR. EDWARD L. TOBINICK, M.D.Inventor's signature [Signature] Date 5.27.98Residence Los Angeles, California Citizenship United States of AmericaPost Office Address 100 UCLA Medical Plaza, Suite 205
Los Angeles, California 90024-6903

Full name of second joint inventor, if any _____

Second Inventor's signature _____ Date _____

Residence _____ Citizenship _____

Post Office Address _____

Applicant or Patentee: DR. EDWARD L. TOBINICK, M.D. Attorney's
Serial or Patent No.: _____ Docket No.:
Filed or Issued: _____ TOBINICK 3.0-006
Title: METHOD OF EMPLOYING A FLASHLAMP FOR REMOVAL OF HAIR, VEINS AND CAPILLARIES

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR**

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark office with regard to the invention entitled METHOD OF EMPLOYING A FLASHLAMP FOR REMOVAL OF HAIR, VEINS AND CAPILLARIES

described in:

- ☒ the specification filed herewith
☐ Application Serial No. _____, filed _____
☐ Patent No. _____, issued _____.

I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern, or organization
☐ persons, concerns, or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

DR. EDWARD L. TOBINICK, M.D.

NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR

X 

Signature of Inventor Signature of Inventor Signature of Inventor

5.27.98

Date Date Date